



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,316	04/21/2004	Joel R. Studin	SDF 04-14	5671

7590
Stuart D. Frenkel
Suite 330
3975 University Drive
Fairfax, VA 22030

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

12/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte JOEL R. STUDIN

Appeal 2009-013624
Application 10/829,316
Technology Center 1600

Oral Hearing Held: September 16, 2010

Before CAROL A. SPIEGEL, TONI R. SCHEINER, and
STEPHEN G. WALSH, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANT:

STUART D. FRENKEL, ESQUIRE
Suite 330
3975 University Drive
Fairfax, Virginia 22030

1 The above-entitled matter came on for hearing on Thursday,
2 September 16, 2010 commencing at 10:17 a.m., at the U.S. Patent and
3 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Victor
4 Lindsay, a Notary Public.

5 THE USHER: Calendar No. 30, Appeal No. 2009-013624,
6 Mr. Frenkel.

7 MR. FRENKEL: Good morning. If I messed up your schedule, I
8 apologize. I've been around here for a long time and traffic never ceases to
9 amaze me or exasperate me.

10 JUDGE SPIEGEL: We've all been in your place.

11 MR. FRENKEL: This is my associate, Jenny Fishman. She's here
12 just to observe, to see what -- how the process works.

13 JUDGE SPIEGEL: You have 20 minutes, and you may begin as you
14 please.

15 MR. FRENKEL: The inventor in this case is Joel Studin. He's been a
16 plastic surgeon in the New York City area for over 20 years. And the case
17 here involves really two sets of claims. Both are related to the treatment of
18 healed wounds. A healed wound is described at page 12, lines 23 through
19 page 13, line 16 on the spec. A healed wound is a wound that has
20 completely closed up, the scab is gone. Now there's a layer of skin, and the
21 process that's beginning is the development of the collagen or the
22 degradation of the collagen. To avoid a scar or to prevent excessive
23 scarring, what we want to do is balance the collagen generation and the
24 collagenase degradation of the skin also as described at page 13, line 7-10 of
25 the spec on the balance of the collagen.

26

1 The two claims or the two sets of claims the Examiner did not require
2 restriction. There's the application of a liquid film on the healed wound
3 which dries to a solid film over the healed wound or the scar. That film can
4 include a medicament or not. Even if it doesn't include a medicament such
5 as steroid or a vitamin, there's still an advantage which is also mentioned in
6 the spec, and this is an important feature. That film dries on the scar and
7 will apply pressure on to the scar. Pressure is a known method of reducing
8 scarring.

9 The other method is simply the application of collagenase --
10 collagenase as a topical application that can be an ointment, gel, anything or
11 in a carrier film as in the first case.

12 JUDGE SCHEINER: That would be Claim 30?

13 MR. FRENKEL: Yes, that's correct. And we are not the first to treat
14 scars. The, the specification at pages 3 through 7 lists all kinds of methods
15 for treating scarring, one of which is pressure, one of which is the
16 application of steroids, the application of ointments, topical gels, and -- all of
17 which have disadvantages. For gels or ointments that means you have to rub
18 that on the wound or scar, and that could be painful under certain
19 circumstances. All the old treatments -- grease or oil film, when wearing
20 clothes that's going to soil your clothing. Pressure requires some kind of
21 contrapment that you've got to wrap around yourself, leg, arm, whatever,
22 that can fall off. Often these pressure devices have gel coatings; the gel can
23 be messy. If the thing comes off your leg, again, you're soiling your
24 clothes. So we're trying to avoid all of that mess and disadvantage on the
25 application of a liquid film that can be either brushed on, sprayed on,
26

1 however, and that film now dries to a dry film that now covers the skin and
2 attaches to the skin and the scar.

3 The Rejection, obviously we think it's a little convoluted. The
4 Examiner's applying two references which he says treat -- would show
5 topical application on skin using these film-forming materials. The first
6 reference, and I'm not sure how to pronounce his name, let's call him
7 Youssefyeh, is treating inflammatory skin conditions with safflower seeds.
8 And in his Patent on page -- column 14, starting at line 19, he lists various
9 methods of how this material can be applied, one of which is a film-forming
10 composition. It doesn't discuss the disadvantages of any of the other
11 treatments, it doesn't really discuss the advantage of a film-forming
12 composition. He's also not treating scars, he's teaching treating an
13 inflammatory disease.

14 The second reference, Mantelle, is also a topical treatment. When I
15 read through this, I'm not even sure if he teaches a dry film.

16 JUDGE SCHEINER: Why don't we talk about -- with Lee because
17 there were two separate rejections, so --

18 MR. FRENKEL: Okay, the Examiner says the primary reference
19 doesn't reach treating the scar, so he's applying Lee as a method of treating
20 scarring. He says that they obviously use the treatment of the primary
21 reference to treat scarring. Well, what's disclosed in Lee is nothing more
22 than what's disclosed in our background of our Application. We're not the
23 first to treat scars. Lee is using pressure which is a very good method of
24 treating scars. Youssefyeh is treating -- not treating scars. He's not treating
25 the condition of collagen formation and the balance of collagen formation
26

1 with a degradation of collagen formation to prevent the scarring on top of
2 the healed wound.

3 JUDGE SCHEINER: Well, the Examiner says that Lee discloses
4 using collagenase, do you agree with that?

5 MR. FRENKEL: Absolutely not. What Lee is doing, if you refer to
6 Claim 30, Lee is enhancing the collagenase in the body by using pressure.
7 Well known, I have no disagreement with that. We -- the Applicant says
8 hey, now we can control that balance by actually applying topically the
9 collagenase on the wound, on the scar, and depending on how far along the
10 scarring is, you can actually control the amount that you're using. Lee is
11 just applying pressure, not a bad method, that is a proven method of
12 working, but surely not as controlled as actually applying the collagenase.

13 JUDGE SCHEINER: So, the Examiner's factually incorrect --

14 MR. FRENKEL: I guess. I mean, the Examiner also applies Lee to
15 tie the references in by saying Lee teaches that scar formation is an
16 inflammatory process. It is not. The initial wound forming is an
17 inflammatory process. Obviously if you're cutting yourself, scraping
18 yourself, burning yourself, there's going to be an initial inflammatory
19 autoimmune response. That's not what we're talking about. We're talking
20 about after that wound has been formed and now it is healed with a layer of
21 skin. That is not an inflammatory process, now we're talking about the
22 formation of collagen and the degradation of collagen and the balance
23 between those two processes. So the combination of Lee with the primary
24 reference I simply don't understand. One isn't going to look to treating scars
25 to the inflammatory process here. And, again, I want to emphasize

26

1 importantly that our broad Claim 1, which just applies the film without any
2 steroid, without any vitamin, without any other medication, works because
3 the film is going to dry around that scar or wound and it's going to apply
4 some pressure. And that's not what's disclosed in any --

5 JUDGE SCHEINER: But the claim requires painting it on as a fluid
6 and allowing it to dry to a --

7 MR. FRENKEL: A flexible -- finite film. The other reference to
8 Mantel, it's essentially the same thing. The Examiner's trying to imply
9 saying that the reference teaches applying topically a film-forming carrier.
10 I'm not sure it does. I think the reference is talking about applying a film to
11 a solid material, like a bandage, and then applying it to the wound. There
12 is -- the reference also teaches treating mucosal tissue, so maybe there's a
13 film or some kind of goop that might be formed on the inside of your mouth.
14 That certainly isn't going to dry to a -- form a dry film. Regardless, the
15 method in the Mantelle Patent does not teach treating scars, does not teach
16 the great advantage of applying a liquid which forms a dry film which can
17 apply pressure, and which can include other materials in it which may
18 further help the balance of the collagenase reaction. That's really all I have
19 to say about it. The references just don't teach our advantages, do not teach
20 the -- do not teach an advantage of this particular carrier mechanism that
21 we've used for treating scars. I will entertain any questions.

22 JUDGE SCHEINER: I don't have anything further.

23 JUDGE SPIEGEL: Thank you, sir. Your case is under advisement.

24 MR. FRENKEL: Quick question: Typically, how long does it take to
25 get a --

26

1 JUDGE SPIEGEL: You'll get this one quickly.

2 MR. FRENKEL: Ma'am?

3 JUDGE SPIEGEL: You'll get this one very quickly.

4 MR. FRENKEL: Thank you very much.

5 JUDGE SPIEGEL: Normally, within three months, but this one will
6 be --

7 MR. FRENKEL: Okay, very good. You guys are moving along,
8 because I just filed a --

9 Whereupon, the proceedings, at 10:27 a.m., were concluded.

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26